PRESS RELEASE

Stockholm & Cambridge, Mass., USA, 13 May 2016

Alprolix® (rFIXFc) approved in the EU for the treatment of haemophilia B

First Fc Fusion therapy approved for haemophilia B in the EU to provide extended protection against bleeds

Swedish Orphan Biovitrum AB (publ) (Sobi™) (STO: SOBI) and Biogen (NASDAQ: BIIB) today announced that the European Commission (EC) has approved Alprolix® (rFIXFc), their extended half-life therapy, for the treatment of haemophilia B in all 28 European Union (EU) member states and maintained its orphan designation. Alprolix is the only recombinant factor IX Fc Fusion protein therapy for haemophilia B to offer people in the EU prolonged protection against bleeding episodes with fewer prophylactic injections.

Alprolix is indicated for both on-demand and prophylaxis treatment of people with haemophilia B in all ages. Prophylactically, it can be administered with an initial dose every seven days or every 10 days with the ability to adjust the dosing interval based on individual response.

“With the approval of Alprolix, people with haemophilia B in Europe now have the potential to experience prolonged protection from bleeds with fewer injections,” said Krassimir Mitchev, M.D., Ph.D., vice president and medical therapeutic area head of Haemophilia at Sobi. “We are working to make Alprolix available in Europe as quickly as possible. Along with Biogen, we’re excited to continue offering innovative therapies to people with haemophilia around the world.”

The EC’s approval of Alprolix was based on results from two global phase 3 clinical trials that demonstrated the efficacy, safety and pharmacokinetics of Alprolix for haemophilia B: the pivotal B-LONG study for previously treated adults and adolescents, and the Kids B-LONG study for previously treated children under age 12. The adverse drug reactions with an incidence of ≥ 0.5 percent for Alprolix were nasopharyngitis (common cold), influenza, arthralgia (joint pain), upper respiratory tract infection, headache, and hypertension. The majority of these events were judged as not related or likely not related to study drug.

“Alprolix has become a meaningful treatment advance for people living with haemophilia B in countries where it is approved and is backed by robust clinical data and the longest real-world experience of any prolonged circulation factor IX therapy to date.” said Gilmore O’Neill, M.D., senior vice president Drug Innovation Units at Biogen. “We’re proud to bring the European haemophilia community one of the first treatment advances in nearly 20 years, and believe the availability of extended half-life therapies in Europe will change the way that many approach treatment.”

Sobi and Biogen collaborate on the development and commercialisation of Alprolix for haemophilia B. Sobi has final development and commercialisation rights in the Sobi territory (essentially Europe, North Africa, Russia and most Middle Eastern markets). Biogen leads development and manufacturing for Alprolix and has commercialisation rights in North America and all other regions in the world excluding the Sobi territory.

About Alprolix®
Alprolix® is a recombinant clotting factor therapy developed for haemophilia B by fusing factor IX to the Fc portion of immunoglobulin G subclass 1, or IgG1 (a protein commonly found in the body). This technology enables Alprolix to use a naturally occurring pathway to prolong the time the therapy remains in the body. While Fc fusion has been used for more than 15 years, Sobi and Biogen are the first companies to utilise it in the treatment of haemophilia.

Alprolix is currently approved for the treatment of haemophilia B in the United States, European Union, Canada, Japan, Australia, New Zealand, and other countries, to provide prolonged protection from bleeds. As with any infused protein, allergic type hypersensitivity reactions and development of inhibitors may occur following administration of Alprolix.

About Haemophilia B
Haemophilia B is caused by having substantially reduced or no factor IX activity, which is needed for normal blood clotting.[1] The World Federation of Hemophilia estimates that approximately 28,000 people are currently diagnosed with haemophilia B worldwide.[2]

People with haemophilia B may experience bleeding episodes in joints and muscles that cause pain, decreased mobility and irreversible joint damage. In the worst cases, these bleeding episodes can cause organ bleeds and life-threatening haemorrhages. Infusions of factor IX temporarily replace clotting factors necessary to resolve bleeding and, when used prophylactically, to prevent new bleeding episodes.[1]

About Sobi™
Sobi is an international specialty healthcare company dedicated to rare diseases. Sobi's mission is to develop and deliver innovative therapies and services to improve the lives of patients. The product portfolio is primarily focused on Haemophilia, Inflammation and Genetic diseases. Sobi also markets a portfolio of specialty and rare disease products across Europe, the Middle East, North Africa and Russia for partner companies. Sobi is a pioneer in biotechnology with world-class capabilities in protein biochemistry and biologics manufacturing. In 2015, Sobi had total revenues of SEK 3.2 billion (USD 385 M) and about 700 employees. The share (STO: SOBI) is listed on NASDAQ OMX Stockholm. More information is available at www.sobi.com.

About Biogen
Through cutting-edge science and medicine, Biogen discovers, develops and delivers worldwide innovative therapies for people living with serious neurological, autoimmune and rare diseases. Founded in 1978, Biogen is one of the world's oldest independent biotechnology companies and patients worldwide benefit from its leading multiple sclerosis and innovative haemophilia therapies. For more information, please visit www.biogen.com and follow us on Twitter.

Biogen Safe Harbor

This press release contains forward-looking statements, including statements about the potential benefits of Alprolix® in haemophilia B, including any changes in the treatment approach for patients with haemophilia B. These forward-looking statements may be accompanied by such words as "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "potential," "project," "target," "will" and other words and terms of similar meaning. You should not place undue reliance on these statements. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including uncertainty of success in commercialization of Alprolix, which may be impacted by, among other things, slower than anticipated acceptance of Alprolix by patients and the medical community, competition in the hemophilia market, the effectiveness of sales and marketing efforts, dependence on third party collaborations and collaborators, problems with the manufacturing process for Alprolix, the occurrence of adverse safety events, difficulties in obtaining or changes in the availability of reimbursement for our products, failure to obtain regulatory approvals in other jurisdictions, failure to protect intellectual property and other proprietary rights, product liability claims and the other risks and uncertainties that are described in the Risk Factors section of our most recent annual or quarterly report and in other reports we have filed with the U.S. Securities and Exchange Commission (SEC). Any forward-looking statements speak only as of the date of this press release and we assume no obligation to update any forward-looking statements, whether as a result of new information, future events, or otherwise.

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[1] World Federation of Hemophilia. About Bleeding Disorders – Frequently Asked Questions. Available at: http://www.wfh.org/en/page.aspx?pid=637#Difference_A_B. Accessed on: February 11, 2016.
[2] World Federation of Hemophilia. Report on the Annual Global Survey 2013. Available at: http://www1.wfh.org/publications/files/pdf-1591.pdf. Accessed on: February 11, 2016.